

**MIAMI BEACH FACES SUNSCREEN 50 BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion**  
**Prime Enterprises Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Miami Beach Faces Sunscreen Lotion 50**

***Active ingredients***

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

***Purpose***

Sunscreen

***Uses***

• helps prevent sunburn • if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

***Warnings***

**For external use only**

**Do not use** on damaged or broken skin

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

***Other Information***

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

***Directions***

• apply liberally 15 minutes before sun exposure

• reapply: • after 80 minutes of swimming or sweating

• immediately after towel drying • at least every 2 hours

• **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses

- children under 6 months: Ask a doctor

***Other information***

- protect this product from excessive heat and direct sun • may stain fabrics.

***Inactive ingredients***

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosensis Leaf Juice, Beta-Carotene, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Crambe Maritima Leaf Extract, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Prunus Armeniaca (Apricot) Kernel Oil, Pseudopterogorgia Elisabethae Plant Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Sorbitan Oleate, Styrene/Acrylates Copolymer, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Zea Mays (Corn) Oil

**Miami Beach Faces Sunscreen Lotion 50**

# MIAMI BEACH™

## FACES SUNSCREEN LOTION

# 50

Broad Spectrum SPF 50  
UVA/UVB Protection

Water Resistant  
(80 Minutes)  
Hypoallergenic

4 FL OZ  
118 mL

Take a little of MIAMI BEACH™ with you!

Presenting our paraben free, non-greasy faces sunscreen lotion. Made with ocean extracts for natural skin moisturizing and protection.  
www.MiamiBeachSun.com - @MBSuncare

### Drug Facts

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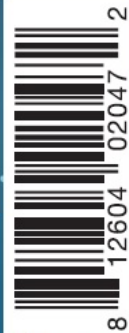
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### Made in USA

From domestic and imported ingredients  
Distributed by: Destination Brands International  
P.O. Box 190586, Miami Beach, FL 33119. 305.592.8565

Official sunscreen of the  
MIAMI BEACH™ Lifeguards



## MIAMI BEACH FACES SUNSCREEN 50 BROAD SPECTRUM SPF 50

avobenzene, homosalate, octisalate, octocrylene lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0255
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.76 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.6 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.28 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.2 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
CARBOMER 1342 (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CRAMBE MARITIMA LEAF (UNII: NO0D12V62B)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CORN OIL (UNII: 8470G57WFM)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
SOLANUM LYCOPERSICUM FRUITING TOP (UNII: X636CG4BH0)	
ROSEMARY (UNII: IJ67X351P9)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

## Product Characteristics

Color	white (White to Off White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0255-3	118 mL in 1 TUBE; Type 0: Not a Combination Product	03/09/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/09/2018	

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**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0255) , manufacture(58443-0255) , label(58443-0255) , analysis(58443-0255)

Revised: 1/2020

Prime Enterprises Inc.